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UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

MDL NO. 1456

Civil Action No. 01-CV-12257-PBS

THIS DOCUMENT RELATES TO:

Judge Patti B. Saris

State of Montana v. Abbott Labs Inc., et al.,
02-CV-12084-PBS

DEFENDANT TAP PHARMACEUTICAL PRODUCTS INC.'S LOCAL RULE 56.1
STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56.1 of the Local Rules of the United States District Court for the District of Massachusetts, Defendant TAP Pharmaceutical Products Inc. ("TAP") submits the following Statement of Undisputed Material Facts in support of its Motion for Summary Judgment:

1. Montana's Second Amended Complaint identifies only the following Subject Drug as to TAP: Prevacid[®]. Ex. 1, Sec. Am. Cmplt. at ¶ 568.
2. Prevacid[®] is a single source, self-administered, brand-name drug. Ex. 2, Expert Declaration of Steven J. Young, dated February 8, 2007 ("Young Decl.") at ¶ 11.
3. Medicaid patients are dispensed self administered drugs through retail pharmacies. *Id.*
4. TAP establishes a "list price" for Prevacid[®] which is the price at which manufacturers sell to direct customers that lack the leverage to negotiate discounts and to wholesalers. *Id.* at ¶ 12.

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5. The list price is commonly referred to as the “wholesale acquisition cost” (“WAC”). *Id.*

6. Manufacturers provide their list prices to wholesalers and report them to companies that publish pricing information. *Id.*

7. The “spread” between Wholesale Acquisition Cost (“WAC”) and Average Wholesale Price (“AWP”) for self-administered, brand-name drugs (like Prevacid®) is consistently between 20 and 25 percent. Ex. 3, Excerpts of the Report of the MDL Court’s Independent Expert, Professor Ernest Berndt (“Berndt Report”) at ¶ 22.

8. “The evolution of the AWP – WAC ‘spread’ for branded self-administered pharmaceuticals is therefore . . . quite understandable, and apparently not the result of any sinister or nefarious conspiracies.” Ex. 3, Berndt Report at ¶ 23.

9. The WAC for Prevacid® is published by pricing compendia alongside its AWP. Ex. 2, Young Decl. at ¶ 14.

10. Direct sales of Prevacid® from TAP to pharmacies are at WAC. Ex. 2, Young Decl. at ¶ 13; *see also* Ex. 4, Excerpts of Hartman Deposition (Aug. 23, 2006) at p. 95; Ex. 5, Excerpts of the Schondelmeyer Report at ¶ 89.

11. TAP’s sales of Prevacid® to wholesalers are also at WAC. Ex. 2, Young Decl. at ¶ 13.

12. Over 88% of TAP’s Prevacid® sales to the retail class of trade, the only Prevacid® purchasers reimbursed by Montana, were at WAC. *See* Ex. 2, Young Decl. at ¶ 14. Since most retail pharmacies purchased Prevacid® at or around WAC, there is no “spread” between the retailer’s cost for Prevacid® and the published WAC. *Id.*

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13. It is widely accepted throughout the pharmaceutical industry that “the published WAC is the most reliable measure of the price at which pharmacies buy branded drugs.” *Id.* at ¶ Sec. F.

14. TAP has no knowledge of the purchase price of purchases of Prevacid[®] by pharmacies from wholesalers. Ex. 2, Young Decl. at ¶ 16. For more than 66% of sales, TAP had no data reflecting wholesaler mark-up to the retail pharmacy. *Id.* at ¶ 18.

15. In addition to the WAC price published in national compendia, Montana had direct access to Prevacid[®]'s Average Sales Price (“ASP”) since the fourth quarter of 2001. *See* Ex. 6, September 28, 2001 Corporate Integrity Agreement between the Office of the Inspector General of the Department of Health and Human Services and TAP Pharmaceutical Products Inc. (“CIA”), Section III. D. 2. (pp. 8-9).

16. Under the CIA, “Average Sales Price” is defined, with respect to each dosage, form, strength and volume of the Government Reimbursed Product, as the average of all final sales prices charged by TAP for Prevacid[®] in the United States to all purchasers, excluding those sales exempt from inclusion in the calculation of “Best Price” for Medicaid Drug Rebate purposes, pursuant to 42 U.S.C. § 1396r-8, and excluding direct sales to hospitals. Ex. 6 at 9,

17. Since the fourth quarter of 2001 and continuing to the present, TAP has provided Montana with its quarterly ASP Reports for all NDCs of Prevacid[®] as well as a detailed methodology of its ASP calculations, a formula created by the Federal Government.¹ Ex. 7, Affidavit of Glenn Weiglein at ¶¶ 3-5; Ex. 8, Excerpt, Buska Dep. 534:18-21 (Dec. 15, 2006) (“Q. [From] what other manufacturers did Montana receive average sale price information? A. I believe I recall seeing stuff from TAP Pharmaceuticals.”)

¹ Pursuant to the Corporate Integrity Agreement, TAP provided Montana with the Average Sales Price of Prevacid[®] on a quarterly basis. *See* Ex. 6, CIA at 8-9.

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18. Montana regulations did not require use of manufacturers' ASP information in determining estimated acquisition cost. Ex. 8, Excerpt, Buska Dep. 559: 5-15 (Dec. 15, 2006).

19. Incorporating ASP information into the pricing logarithm for Montana Medicaid would require a manual process. *Id.* at 552:16-22; 558:18-21. Montana Medicaid chose not to use the ASP information provided by TAP. *Id.*, at 572:3-19.

20. Various Montana state entities also have been able to purchase drugs at significant discounts through direct contracts with TAP. *See* Ex. 2, Young Decl. at ¶ 32.

21. The Montana Department of Corrections, part of the same agency as the Montana Department of Health and Human Services, purchased Prevacid® at significant discounts. *Id.* at ¶ 30.

22. Additionally, the Montana Department of Public Health is qualified to purchase Prevacid® at the Public Health Service Act's mandated discount of 15.1% off AMP. *Id.* at ¶¶ 31-32. The Montana Department of Public Health has participated in this discount program available under Section 340B of the Public Health Service Act since at least 1997. *Id.*

23. In addition to these two Departments, the state has had access to the publicly available Department of Veteran Affairs pricing for Prevacid®, which, under the Veterans Healthcare Act, is priced at a 24% discount off the average price at which the TAP sells Prevacid® to non-Federal customers. *Id.* at ¶ 33. Montana could have determined non-Federal Average Manufacturer Price using the standard formula: Non-Federal Average Manufacturer Price=VA price/76 (*i.e.*, 100-76% discount).

24. Montana also has been eligible for federally-mandated rebates on Prevacid® since its introduction in 1995. *See* Ex. 9, 42 U.S.C. § 1396r-8 et seq., Omnibus Budget Reconciliation Act of 1990 ("OBRA 1990").

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25. Under the provisions of OBRA 1990, Montana was eligible for rebates of the greater of either (1) a specified percent (currently 15.1 percent) of Average Manufacturer's Price ("AMP") or (2) the difference between the "best price" and adjusted by the CPI-U based on launch date and current quarter AMP.² *See* Ex. 2, Young Decl. at ¶ 24.

26. These rebates allowed the Montana Medicaid program to procure Prevacid® at a substantial discount.³ *See* Ex. 10, 136 CONG. REC. S12,954 (1990) (statement of Sen. Pryor); Ex. 2, Young Decl. at ¶¶ 24-27. As a result of these rebates, the net amount Medicaid and the patient paid the retail pharmacy, less the rebate paid by TAP to Medicaid (the "Net Effective Payment After Rebate") was below the WAC for Prevacid®. *Id.* at ¶¶ 25-26.

27. In addition to these federally-mandated rebates, in 2004 Montana entered into supplemental rebate agreements with TAP. Ex. 2, Young Decl. at ¶¶ 24, 28.

28. The combination of these two rebate programs assures Montana's net price for Prevacid® is well below the price paid by the retail market. *Id.* at ¶¶ 24-27, Sec. F ("In all cases the Net Effective Reimbursement After Rebate paid by the State for Prevacid® was below the WAC. . . . The comparison establishes that Medicaid ultimately paid an amount that was well below the price paid by the retail market for Prevacid®.").

² For the quarters beginning January 1, 1995 through December 31, 1995, the Rebate was calculated as the greater of either (1) 15.2 percent of AMP (after deducting customary prompt payment discounts) or (2) the difference between AMP and the "best price" – the lowest price available from the manufacturer to any wholesaler, retailer, nonprofit entity, or governmental entity within the United States. For all quarters beginning after December 31, 1995, the Rebate was calculated as the greater of either (1) 15.1 percent of AMP (after deducting customary prompt payment discounts) or (2) the difference between AMP and the "best price." *See* Ex. 9, OBRA 1990, 42 U.S.C. § 1396r-8(c)(1)(A, B).

³ Statement of Senator Pryor regarding the purpose of the rebate provisions of OBRA '90. Ex. 10, 136 CONG. REC. S12,954 (1990). *See also* Ex. 11, 137 CONG. REC. S6831 (1991) ("In effect, the Federal Government told the pharmaceutical industry that since the Federal/State Medicaid Program pays for 13 percent of all drug purchases, this program should be charged the lowest price that the companies offer some private purchasers.") (statement of Sen. Durenberger); Ex. 12, 137 CONG. REC. S10,424 (1991) ("These provisions protect American taxpayers by enabling the Medicaid Program to obtain prescription drugs at prices as low as those offered to the best customers of drug manufacturers.") (statement of Sen. Bentsen).

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29. Indeed, the combination of the federal and supplemental rebate has substantially reduced the overall cost of Prevacid® to Montana. *Id.* at ¶ 28 (through negotiating Supplemental Rebates, “the state achieved a Net Effective Payment . . . of up to 62 % below Prevacid®’s WAC.”).

30. The Montana Medicaid statute employs a lesser of methodology for reimbursement. Medicaid pharmacy reimbursement is paid at the lower of (1) usual and customary charge; (2) maximum allowable charge; or (3) estimated acquisition cost. Estimated acquisition cost is defined as the direct price charged by manufacturers to retailer or, if no direct price is available, the AWP-10% prior to July 2002 and AWP-15% after July 2002. *Id.* at ¶ 19. Under this provision Montana Medicaid should have used the published direct price if it were available. *Id.* at ¶ 20.

31. A price designated as direct price was published for Prevacid® back until at least July of 1998. *Id.* Montana Medicaid’s claim processor, ACS, had those direct prices in the claims processing system’s reimbursement table and should have used this price for reimbursement as required by the Montana Medicaid statute. *Id.*

32. A substantial number of Montana’s reimbursements for Prevacid® were not made using the percentage off AWP formula. Ex. 2, Young Decl. at ¶ 22.

33. Manufacturers cannot manipulate the “spread” for drugs reimbursed on a non-AWP-based formula. Montana’s own expert explained the AWP manipulation theory applies only “[i]f a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers’ profits,” noting that “[t]o the extent that a manufacturer controls the ‘spread,’ it controls customers’ profits.” See Ex. 13, Declaration of Raymond S. Hartman, dated June 13, 2006 (“MT Hartman Decl.”) at ¶ 13.

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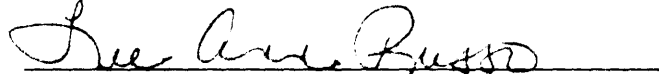
34. Moreover, it is impossible to market any potential “spread” on Prevacid® because retail pharmacies “cannot freely substitute between different patent-protected single-source brands, unless explicit permission is first obtained from the prescribing physician”. *See* Berndt Report at ¶ 42.

35. The difference between WAC and Montana Medicaid’s AWP-based reimbursement level for Prevacid® “is a narrow range normally equal to or less than 8% of the published WAC.” Ex. 2, Young Decl. at Sec. F.

36. Reimbursements for Prevacid® using Montana Medicaid’s EAC likely underpaid the retail pharmacies for their costs related to the Prevacid® they dispensed. *Id.*

Dated: February 8, 2007

Respectfully submitted,



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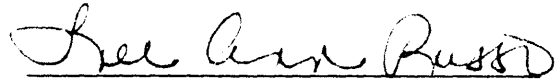
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CERTIFICATE OF SERVICE

I hereby certify that on February 8, 2007, I caused a true and correct copy of the foregoing **DEFENDANT TAP PHARMACEUTICAL PRODUCTS INC.'S LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT** to be served on liaison counsel (identified below) via Federal Express next day delivery.


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